K090434

JUL - 6 2009

5-510(k) Summary

owner's name:	Bego Bremer Goldschlägerei GmbH
address:	Wilhelm-Herbst-Strasse 1 28359 Bremen Germany
phone:	+49-241 2028 138
fax numbers:	+49-241 2028 44 138
name of contact person:	Michael Essler
date the summary was prepared:	2007-12-15
Establishment Registration number:	3007074187
name of the device:	BeCe Press
trade or proprietary name:	BeCe Press
the classification name:	Porcelain Powder for Clincal use (21 CFR 872.6660 Product Code EIH)
Legally marketed device to which your firm is claiming equivalence	
Company:	Ivoclar Vivadent Inc.
Device:	IPS InLine PoM System
510(k) No.:	K071848

Intended use/ Indications for Use

BeCe PRESS Ceramic system permits restorations of natural teeth in the form of metal-ceramic crowns and bridges. The pressable ceramics can be pressed to frames made of precious or non-precious alloys with a CTE of 13.8 to 14.6 x 10-6 K-1 (20ºC to 500ºC) after application of opaquer. Applications range from single tooth crowns to various size bridges.

Technology characteristics

BeCe PRESS is a dental ceramic system for veneering metal copings and frameworks using a press on alloy technique. The pressing ingots are composed of a two-phase leucite reinforced silicate ceramic.

The restoration is processed according to the lost wax technique. The opaqued mteal framework is first waxed-up in the desired shape an function and invested. After burning out of the wax the heated, ductile BeCe PRESS ceramic is pressed into the previously created hollow space by a special ceramic press-furnace. After devesting, the restoration can be individually characterized by shade/stains and glaze materials with accompanying liquids

Performance data

Ceramic	Type	Class	CTE 2 x firing (25 - 500 °C) (77 - 932 °F) [x 10⁻⁶K⁻¹]	CTE 4 x firing (25 - 500 °C) (77 - 932 °F) [x 10⁻⁶K⁻¹]	Tg 2 x / 4 x Firing [°C] / [°F]	Chem. solubility [µg/cm²]		3-point flexural strength [Mpa]	
						Measure-ment	ISO 6872	Measure-ment	ISO 6872
BeCe PRESS Ceramic	II	1	13.0	13.0	590 / 1094	≤ 20	< 100	≥ 125	> 100

Contraindications

BeCe PRESS is intended solely for dental applications,used by dental technicians and trained persons/people. This product is not designed to be used with restorations that do not have a metal substructure or frame. It is strongly recommended that only metal frameworks expressly approved by BEGO should be used for the press on alloy technique with BeCe PRESS ceramics. All other alloys not tested by BEGO must be tested by the user before any restoration for a patient is created. Users are solely responsible for subsequent use in all cases.

As such the BeCe Press can be concluded substantial equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Michael Essler
Product Manager Ceramics
BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Wilhelm-Herbst-Strasse 1
Bremen
GERMANY 28359

Re: K090434
Trade/Device Name: BeCe Press
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: May 15, 2009
Received: May 27, 2009

Dear Mr. Essler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/Centers_Offices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090434

Device Name: **BeCe Press**

Indications of use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Hei Marley Soe NSP

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K090434